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acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, wherein the stringent conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

17. A method for producing a recombinant TCL-1 protein comprising:

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(a) culturing a host cell transformed with a recombinant expression vector comprising a nucleotide sequence that encodes a TCL-1 protein such that the TCL-1 protein is expressed by the cell; and

(b) recovering the expressed TCL-1 gene protein, wherein a first nucleic acid molecule consisting of said nucleotide sequence hybridizes under stringent conditions to a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, and wherein the stringent conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

REMARKS

Claims 5, 6, 13, and 17 have been amended to more particularly point out and distinctly claim that which Applicants regard as the invention. A marked up version of the claims showing the amendments is attached hereto as Exhibit A. The Examiner has withdrawn from consideration claims 11, 12, 14-16, 22-63, and 65, as being drawn to a non-elected species. Claims 11, 12, 14-16, 22-63, and 65 are canceled without prejudice. Applicants reserve the right to prosecute the subject matter of the canceled claims in one or more related applications. A copy of all the claims, as amended, is attached hereto as Exhibit B. The amendments to the claims are fully supported in the specification as filed, see, e.g.,

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page 9, lines 28-32; page 11, lines 13-14; page 14, lines 1-5, page 15, lines 3-7; 11-15; and page 20, lines 3-8. No new matter is added.

A Substitute Sequence Listing is submitted herewith to replace the Sequence Listing on pages 66 to 73 of the specification. The specification has been amended to recite the correct sequence identifier. A marked up version of the paragraph showing the amendment is attached hereto as Exhibit C.

1. The Objection to the Specification

The specification is objected because it does not comply with the requirements of 37 C.F.R § 1.821(a)(1) and (a)(2). In response, Applicants submit concurrently herewith a Transmittal of Substitute Sequence Listing, a computer readable form of the Substitute Sequence Listing and a paper copy of the Sequence Listing. The Sequence Listing on pages 66 to 73 of the specification is replaced by the Substitute Sequence Listing submitted herewith. The specification has also been amended on page 8 to recite the correct sequence identifier. In view of the foregoing, Applicants submit that the requirements of 37 C.F.R § 1.821(a)(1) and (a)(2) are met and request that the objection be withdrawn.

2. The Rejections Under 35 U.S.C. § 112, First Paragraph Are Obviated

Claims 5, 13, and 17 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner contends that the rejected claims encompass a large number of polypeptides for different biological species and the specification lacks guidance regarding possible structural/functional characteristics which might be conserved across biological species.

In response, Applicants have amended claims 5, 13, and 17. The amendment to the claims added the requirement that the claimed TCL-1 protein is encoded by a nucleic

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acid molecule which is highly homologous to the human TCL-1 cDNA (SEQ ID NO: 1) in that the nucleic acid molecule hybridizes to the complement of human TCL-1 cDNA under stringent hybridization conditions. The applicable stringent conditions for hybridization, including the set of conditions recited in the amended claims, are provided in the specification on page 15, lines 14-23. Moreover, as described on page 14, line 1 to page 15, line 23 of the specification, the nucleic acids encoding TCL-1 from other species, such as porcine, bovine, feline, avian, equine, and canine species, can be obtained by using the TCL-1 gene of the invention as a hybridization probe to identify the corresponding TCL-1 gene in a DNA library. Applicants submit that the TCL-1 proteins recited by the amended claims are thus those encoded by highly homologous nucleic acid molecules.

According to the Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement (Federal Register v. 66, no. 4, pages 1099-1111, January 5, 2001, the "Guidelines"), the written description requirement may be satisfied by disclosure of relevant, identifying characteristics, i.e., structure or other physical or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Applicants respectfully submit that the chemical structure of proteins is well known, and that the variation of amino acid sequence among species within the claimed genus is properly defined by (1) the universal codon usage table and (2) the functional characteristics of the nucleic acids that specifically binds under defined hybridizing conditions to another nucleic acid molecule with defined nucleotide sequence. One of skill in the art would recognize from the combination of identifying structural and functional characteristics disclosed in the specification that Applicants have possession of the claimed

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genus of TCL-1 proteins. As such, Applicants submit that adequate written description has been provided, and the rejection of claims 5, 13, and 17 is obviated.

Claim 7 is rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner contends that claim 7 may encompass an enormous number of polypeptide fragments which can be bound by a TCL-1 specific antibody, but that the specification lacks description of such polypeptide fragments. The Examiner also asserts that not all polypeptides are antigenic or are antigenic in all forms of presentations. Applicants respectfully disagree with the rejection.

According to applicable case law, in order to provide an adequate written description, the specification must reasonably convey to the artisan that the inventor had possession at that time of the claimed subject matter. While a patent applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the applicant invented what is claimed. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991)(citing In re Gosteli, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989)). Moreover, as discussed above, the Guidelines indicate that the written description requirement may be satisfied by disclosure of relevant, identifying characteristics, such as a sequence, structure, binding affinity, binding specificity, as well as antibody cross-reactivity (see Footnote 39 of the Guidelines). Applicants submit that, although the number of species within the genus is large, one of ordinary skill can readily recognize the claimed genus of TCL-1 protein fragments from the combination of disclosed structural characteristics of claim 6 (i.e., SEQ ID NO: 2), and the functional characteristics disclosed in the specification regarding the specific binding of anti-TCL-1 antibodies.

In fact, the skilled person can readily make and determine whether a TCL-1 fragment falls within claim 7 by, for example, the limited protease digestion of a TCL-1

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protein or expressing a TCL-1 fragment recombinantly in a cell, and detecting the binding of an anti-TCL-1 antibody to the TCL-1 fragment (see, for example, the use of Western blotting with the rabbit anti-TCL-1 antibody as disclosed on page 58, lines 18-24). Any TCL-1 fragment that is too short to bind or cannot bind to an anti-TCL1 antibody are not included in claim 7, and can be readily identified. "The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention." Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421, 5 U.S.P.Q.2d 1194, 1197 (Fed. Cir. 1987), cert. denied, 486 U.S. 1008 (1988). Applicants submit that the skilled artisan can make and use the claimed fragments of the TCL-1 protein without undue experimentation based on the disclosures in the specification. In sum, Applicants submit that there is sufficient written description to inform a skilled artisan that Applicants were in possession of the claimed subject matter of claim 7. As such, Applicants submit that the rejection of claim 7 is in error and should be withdrawn.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejections under section 112, first paragraph.

3. The Rejection Under 35 U.S.C. § 112, Second Paragraph, Are Obviated

Claim 6 is rejected under 35 U.S.C. § 112, Second Paragraph, for indefiniteness. Allegedly, claim 6 specifies a polypeptide having the amino acid sequence of SEQ ID NO: 2 from residue 1 to 114, while SEQ ID NO: 2 has 113 residues. In response, claim 6 has been amended to recite the correct amino acid residue number. Therefore, Applicants respectfully request the withdrawal of this rejection.

CONCLUSION



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Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the instant application. Withdrawal of the Examiner's rejections and allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

Respectfully submitted,

Date: July 16, 2001

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Enclosure

EXHIBIT A
MARKED VERSION OF THE CLAIMS
U.S. PATENT APPLICATION SERIAL NO. 09/441,242

5 (amended). An isolated TCL-1 protein comprising an amino acid sequence encoded by a first nucleic acid that hybridizes under stringent conditions to a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, wherein the stringent conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

6 (amended). [The] An isolated TCL-1 protein [of Claim 5 having] comprising the amino acid sequence of SEQ ID NO: 2 from amino acid number 1 to [114]113.

13 (amended). A fusion protein comprising a TCL-1 protein sequence of at least 10 amino acids linked to a non-TCL-1 protein sequence, wherein the TCL-1 protein sequence is encoded by a first nucleic acid that hybridizes under stringent conditions to a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, wherein the stringent conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

17(amended). A method for producing a recombinant TCL-1 protein comprising:

(a) culturing a host cell transformed with a recombinant expression vector comprising a nucleotide sequence that encodes [encoding] a TCL-1 protein such that the TCL-1 protein is expressed by the cell; and

(b) recovering the expressed TCL-1 gene protein, wherein a first nucleic acid molecule consisting of said nucleotide sequence hybridizes under stringent conditions to a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, and wherein the stringent conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

EXHIBIT B
THE CLAIMS WHICH WILL BE PENDING UPON ENTRY OF THE PRESENT
AMENDMENT(Filed July 16, 2001)
U.S. PATENT APPLICATION SERIAL NO. 09/441,242

5. An isolated TCL-1 protein comprising an amino acid sequence encoded by a first nucleic acid that hybridizes under stringent conditions to a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, wherein the stringent conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

6. An isolated TCL-1 protein comprising the amino acid sequence of SEQ ID NO: 2 from amino acid number 1 to 113.

7. A fragment of the protein of Claim 6 which can be specifically bound by an antibody to a TCL-1 protein.

13. A fusion protein comprising a TCL-1 protein sequence of at least 10 amino acids linked to a non-TCL-1 protein sequence, wherein the TCL-1 protein sequence is encoded by a first nucleic acid that hybridizes under stringent conditions to a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, wherein the stringent conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

17. A method for producing a recombinant TCL-1 protein comprising:

(a) culturing a host cell transformed with a recombinant expression vector comprising a nucleotide sequence that encodes a TCL-1 protein such that the TCL-1 protein is expressed by the cell; and

(b) recovering the expressed TCL-1 gene protein,
wherein a first nucleic acid molecule consisting of said nucleotide sequence hybridizes under stringent conditions to a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387, and wherein the stringent

conditions comprise washing at 50°C in 0.015 M NaCl, 0.0015 M sodium citrate, and 0.1% sodium dodecyl sulfate.

18. An isolated protein comprising an amino acid sequence having at least 70% amino acid sequence identity to the amino acid sequence depicted in SEQ ID NO: 2, over a contiguous sequence of at least 25 amino acids.

19. An isolated protein comprising an amino acid sequence having at least 70% amino acid sequence identity to the amino acid sequence depicted in SEQ ID NO: 2, over a contiguous sequence of at least 50 amino acids.

EXHIBIT C
MARKED VERSION OF AN AMENDED PARAGRAPH IN THE SPECIFICATION
U.S. PATENT APPLICATION SERIAL NO. 09/441,242
(ATTORNEY DOCKET 8666-008)

On page 8, please amend the paragraph beginning "Figure 8" as follows:

Figure 8: Shared sequence homology between TCL-1 protein [(SEQ ID NO: 8)] (SEQ ID NO: 12) and Mature T-Cell Proliferative 1 (MTCP1) protein (SEQ ID NO: 4).